

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 159035-5 DK	FOR FURTHER ACTION		See item 4 below
International application No. PCT/IL2005/000300	International filing date (day/month/year) 16 March 2005 (16.03.2005)	Priority date (day/month/year)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant OR-NIM MEDICAL LTD.			

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).		
2.	This REPORT consists of a total of 6 sheets, including this cover sheet.  In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.		
3.	This report contains indications relating to the following items:		
	<input checked="" type="checkbox"/> Box No. I	Basis of the report	
	<input type="checkbox"/> Box No. II	Priority	
	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	
	<input type="checkbox"/> Box No. IV	Lack of unity of invention	
	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
	<input type="checkbox"/> Box No. VI	Certain documents cited	
	<input type="checkbox"/> Box No. VII	Certain defects in the international application	
	<input type="checkbox"/> Box No. VIII	Certain observations on the international application	
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).		

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70	Date of issuance of this report 18 September 2007 (18.09.2007)
	Authorized officer  Simin Baharlou  e-mail: pt09.pct@wipo.int

10/592,318

# PATENT COOPERATION TREATY

**REC'D 27 MAR 2006**  
 WIPO PCT

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:  
Svetlana Shtadler  
REINHOLD COHN AND PARTNERS  
P.O. BOX 4060  
TEL AVIV, ISRAEL 61040

Date of mailing  
(day/month/year) **23 MAR 2006**

Applicant's or agent's file reference

**FOR FURTHER ACTION**

See paragraph 2 below

159035-5 DK

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/IL05/00300

16 March 2005 (16.03.2005)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61B 08/00 and US Cl.: 600/438

Applicant

OR-NIM MEDICAL LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

#### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
Facsimile No. (571) 273-3201

Date of completion of this opinion  
17 January 2006 (17.01.2006)

Authorized officer  
Marvin Lateef

Telephone No. 703-308-0858

Form PCT/ISA/237 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IL05/00300

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/IL05/00300

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>5-8,10-35,38-39,42-48,55 - 70</u>	YES
	Claims <u>1-4,9,36-37,40-41,49-54</u>	NO
Inventive step (IS)	Claims <u>18-20, 38-39,45-46,60-65</u>	YES
	Claims <u>1-17,21-37,40-44,47-59, 66-70</u>	NO
Industrial applicability (IA)	Claims <u>1 - 70</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Please See Continuation Sheet

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/IL05/00300

**Supplemental Box**  
In case the space in any of the preceding boxes is not sufficient.

**V. 2. Citations and Explanations:**

Claims 1 - 4, 9, 36 - 37, 40 - 41, 49 - 54 lack novelty under PCT Article 33(2) as being anticipated by Sfez et al (US6815694) which teaches that an optical transmission and detection unit may be operated in a method using a system having ultrasound acoustic tagging of a targeted region such that the optical illumination and detection unit 14 and 18 may be operated with scanned ultrasound optimized to differing focal depths may be operated with at least two different phase sequences so as to change effective photon path lengths and measure differences in absorption/attenuation so that the control unit may act to measure the blood volume or oxygen saturation in a region of interest.

Claims 5-8, 10, 27 - 35, 68 - 70 lack an inventive step under PCT Article 33(3) as being obvious over Sfez et al in view of Godik (US6,002,958) since whereas the former is silent as to duty cycle variations in the acoustic radiation, it would have been obvious in view of the latter col. 5 lines 12 - 34 to vary the duty cycle as shown in Figs. 2 - 3 in order to optimally differentiate differing tissue types, and to provide a common opto-acoustic support unit encircling the test subject and having a plurality of selectable light ports as shown for example in Fig. 4.

Claims 11 - 17, 48, 55 - 57, 67 lack an inventive step under PCT Article 33(3) as being obvious over Sfez et al in view of Tomlinson, Jr. et al (US5,212,667) insofar as whereas the former is silent as to photon tagging efficiency, it would have been obvious in view of the latter col. 5 line 42 - col. 6 line 60 to use ultrasound at different amplitudes in the pulse sequences of the former during measurement in order to provide differing photon efficiencies in order to provide a reference standard for measurement, and to use speckle interference analysis to obtain the measured result.

Claims 21 - 26, 47, 58 - 59, 66 lack an inventive step under PCT Article 33(3) as being obvious over Sfez et al in view of Tomlinson, Jr. et al, further in view of Wang (US 6041248) or Dolfi et al (US5174298) since in the case of the former, it would have been obvious to provide frequency-encoding into Sfez et al in order to provide dimensional specificity to the measurement, or in the case of the latter, it would have been obvious in view of Dolfi et al col. 2 lines 50 - 54 to use differing frequencies in the pulse sequences of Sfez et al in order to improve the signal-to-noise ratio. In the case of Dolfi et al, optical heterodyning is used with a local oscillator to generate measurement data.

Claims 42 - 44 lack an inventive step under PCT Article 33(3) as being obvious over Sfez et al in view of Irion et al (US6390978). Whereas the former does not teach use of annular interspersed array structure, it would have been obvious in view of the latter col. 13 lines 13 - 25 to use an interspersed optic array and annular ultrasound array construct in order to provide focused ultrasound co-linear with diffused collection.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Claims 18 - 20, 38 - 39, 45 - 46, 60 - 65 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest using continuously chirped acoustic radiation having at least two different values of a gradient of the chirping or the selection of optical coupling and light guide lengths so as to satisfy a coherence length requirement for interference operation between tagged and untagged photons, or the adaptation of the system into a jugular vein measurement device allowing insertion of at least part of the unit into the external ear canal.

Claims 1-70 meet the criteria set out in PCT Article 33(4) and thus have industrial applicability because the subject matter can be made or used in industry.

# PATENT COOPERATION TREATY

10/593318

REC'D 27 MAR 2006  
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Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
Facsimile No. (571) 273-3201

Date of completion of this opinion  
17 January 2006 (17.01.2006)

Authorized officer  
*[Signature]*  
Marvin Lateef

Telephone No. 703-308-0858

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	Claims <u>NONE</u>	NO

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